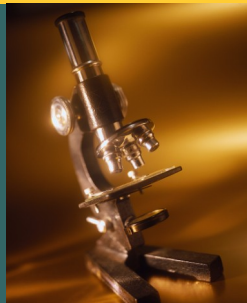


Winter 2010



NORTH DAKOTA DEPARTMENT OF HEALTH  
DIVISION OF HEALTH FACILITIES

# CLIA BITS



## Most Commonly Cited Deficiencies

Following is a breakdown of the most common deficiencies cited in the North Dakota CLIA program from Oct. 1, 2008, through Sept. 30, 2009.

**D2016** — Success Participation. Each laboratory performing non-waived testing must successfully participate in an approved proficiency testing program.

**D5217** — Evaluation of Proficiency Testing Performance. The laboratory must verify the accuracy of any non-regulated analyte at least twice annually.

**D2000** — Enrollment and Testing Samples. The laboratory must be enrolled in an approved proficiency testing program for all non-waived regulated analytes.

**D6088** — Laboratory Director Responsibilities. The laboratory director must ensure the laboratory is enrolled in an approved proficiency testing program for all non-waived regulated analytes.

**D3031** — Retention Requirements. The laboratory must retain quality control and patient test records (including instrument printouts if the instrument is not interfaced to a laboratory information system) for at least two years.

**D5415** — Test systems, Equipment, Instruments, Reagents, Materials and Supplies. Reagents, solutions, culture media, control materials and other supplies must be labeled to indicate the following: identity, storage requirements, and preparation and expiration dates.

**D5417** — Test systems, Equipment, Instruments, Reagents, Materials and Supplies. Reagents, solutions, culture media, control materials and other supplies must not be used when they have exceeded their expiration date, have deteriorated or are of substandard quality.

**D5421** — Establishment and Verification of Performance. Each laboratory that introduces a test method must demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: accuracy, precision and reportable range of test results. The laboratory also must verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

### Inside this issue:

Most Commonly Cited Deficiencies	1
Laboratory Personnel Mandatory Deficiencies	2
Q & A	2

*If you would like to receive CLIA Bits electronically, please send your e-mail address and company name to Bridget Weidner at [bweidner@nd.gov](mailto:bweidner@nd.gov).*

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## Questions and Answers (Q & A)

CMS provides specialized CLIA training courses for state surveyors. During these training courses, surveyors from across the country ask CMS staff questions regarding the survey process. Although the questions and answers do not represent official CMS policy, they contain valuable information regarding the survey process. The Q & A is a regular feature of the CLIA Bits newsletter. We hope you find this information interesting and useful. Readers are welcome to submit questions to [bweidner@nd.gov](mailto:bweidner@nd.gov) or [sheilman@nd.gov](mailto:sheilman@nd.gov).

- Q. What is a condition-level deficiency?
- A. Non-compliance with one or more condition-level requirements. A condition-level deficiency is a more serious deficiency that is required to be corrected within a specific timeframe, or CMS can impose sanctions on the CLIA certificate. Principal sanctions include limitation, suspension or revocation of the CLIA certificate.
- Q. If a physician completes a 20 continuing medical education (CME) approved course for laboratory directors, is he/she also qualified to be the technical consultant?
- A. Not necessarily. A physician must have at least one year of laboratory training or experience or both in non-waived testing in the designated specialty area for which the technical consultant is responsible in order to qualify as the laboratory's technical consultant. The physician must provide documented evidence of the one year of laboratory training or experience (ordering laboratory tests does not qualify as laboratory experience).
- Q. Our laboratory director resigned and another one of our physicians is going to fill the position after completing an approved laboratory director course. What do we do in the meantime?
- A. The laboratory must immediately fill the laboratory director position or cease testing until the position can be filled. Failure to have a qualified laboratory director is a condition-level deficiency.

## Laboratory Personnel Mandatory Deficiencies

A laboratory performing non-waived tests must be in compliance with the CLIA personnel requirements or face mandatory condition-level deficiencies. A laboratory performing moderate complexity testing is required to staff the following positions: laboratory director, clinical consultant, technical consultant and testing personnel. A laboratory performing high complexity testing is required to staff the following positions: laboratory director, clinical consultant, technical supervisor, general supervisor and testing personnel. An individual may fill more than one position if he or she is qualified. A laboratory will be considered in compliance if all the required positions are filled; the individual meets the required qualifications for the position based on education, training and experience; and the individual fulfills the responsibilities of the position.



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